

## Food and Drug Administration, HHS

## § 524.1580c

corneal ulcers. They should not be used until infection is under control and corneal regeneration is well underway. Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use on antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly *Monilia*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[43 FR 40456, Sept. 12, 1978]

### § 524.1484j [Reserved]

### § 524.1484k Neomycin sulfate, prednisolone, tetracaine, and squalane topical-otic suspension.

(a) *Specifications*. Each milliliter of suspension contains 5 milligrams neomycin sulfate (equivalent to 3.5 milligrams neomycin base), 2 milligrams prednisolone, 5 milligrams tetracaine, and 0.25 milliliter squalane.

(b) *Sponsor*. See 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 2 to 3 applications daily or as needed.

(2) *Indications for use*. Indicated for use in dogs and cats for treating acute otitis externa and as adjunctive therapy in management of chronic otitis externa. The product may also be used for treating moist dermatitis in dogs.

(3) *Limitations*. Tetracaine and neomycin have the potential to sensitize. If signs of irritation or sensitivity develop, discontinue use. Prolonged use of this product may result in overgrowth of nonsusceptible organisms. If new infections due to bacteria or fungi appear during therapy, appropriate measures should be taken. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 5265, Feb. 4, 1983; 48 FR 8055, Feb. 25, 1983]

### § 524.1580 Nitrofurazone ophthalmic and topical dosage forms.

#### § 524.1580a [Reserved]

#### § 524.1580b Nitrofurazone ointment.

(a) *Specifications*. The drug contains 0.2 percent nitrofurazone in a water-soluble base.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter.

(1) See Nos. 000010, 000069, 050749, 054925, 058005, and 061623 for use on dogs, cats, or horses.

(2) See No. 017135 for use on dogs and horses.

(3) See Nos. 017153 and 058829 for use on horses.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount*. Apply directly on the lesion with a spatula or first place on a piece of gauze. The preparation should remain on the lesion for at least 24 hours. Use of a bandage is optional.

(2) *Indications for use*. For prevention or treatment of surface bacterial infections of wounds, burns, and cutaneous ulcers of dogs, cats, or horses.

(3) *Limitations*. For use only on dogs, cats, and horses. Do not use in horses intended for human consumption. Federal law prohibits the use of this product in food-producing animals. In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.

[46 FR 43402, June 27, 1980]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 524.1580b, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at [www.fdsys.gov](http://www.fdsys.gov).

### § 524.1580c Nitrofurazone soluble powder.

(a) *Specifications*. The drug contains 0.2 percent nitrofurazone in a water-soluble base.

(b) *Sponsor*. See Nos. 000010, 000069, and 050749 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Apply several times daily to the lesion or affected area from the plastic squeeze bottle.

(2) *Indications for use*. For prevention or treatment of surface bacterial infections of wounds, burns, skin ulcers, and abscesses after incision.<sup>1</sup>

(3) *Limitations*. In case of deep or puncture wounds or serious burns, use only as recommended by veterinarian.

## § 524.1580d

If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian. For use only on dogs, cats, and horses (not for food use).<sup>1</sup>

[45 FR 43402, June 27, 1980, as amended at 47 FR 43368, Oct. 1, 1982; 48 FR 28984, June 24, 1983; 53 FR 40728, Oct. 18, 1988; 54 FR 30542, July 21, 1989; 56 FR 50653, Oct. 8, 1991; 59 FR 33197, June 28, 1994; 60 FR 55659, Nov. 2, 1995; 62 FR 35077, June 30, 1997]

EFFECTIVE DATE NOTE: At 76 FR 17778, Mar. 31, 2011, § 524.1580c was amended by removing “Nos. 000010, 000069, and 050749” and in its place adding “Nos. 000010 and 000069”, effective April 11, 2011.

## § 524.1580d [Reserved]

### § 524.1580e Nitrofurazone ointment with butacaine sulfate.

(a) *Specifications.* The drug contains 0.2 percent nitrofurazone and 0.5 percent butacaine sulfate in a water-soluble base.

(b) *Sponsor.* See No. 054925 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Indications for use.* For prevention or treatment of surface bacterial infections of ears, wounds, burns, and cutaneous ulcers of dogs, cats, and horses.<sup>1</sup>

(2) *Limitations.* Apply directly on the lesion with a spatula or first place on a piece of gauze. Use of a bandage is optional. The preparation should remain on the lesion for at least 24 hours. The dressing may be changed several times daily or left on the lesion for a longer period. For use only on dogs, cats, and horses (not for food use). In case of deep or puncture wounds or serious burns, use only as recommended by a veterinarian. If redness, irritation, or swelling persists or increases, discontinue use; consult veterinarian.<sup>1</sup>

[49 FR 9417, Mar. 13, 1984, as amended at 71 FR 13542, Mar. 16, 2006]

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

## 21 CFR Ch. I (4–1–11 Edition)

### § 524.1600 Nystatin ophthalmic and topical dosage forms.

#### § 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone acetonide ointment.

(a) *Specifications.* Each milliliter of petrolatum base or each gram of vanishing cream base ointment contains: 100,000 units of nystatin; neomycin sulfate equivalent to 2.5 milligrams of neomycin base; 2,500 units of thiostrepton; and 1.0 milligram of triamcinolone acetonide.

(b) *Sponsors.* For petrolatum base ointments see 000069, 000856, 025463, 053501, and 054925 in § 510.600(c) of this chapter. For vanishing cream base ointments see Nos. 025463, 053501, and 054925.

(c) *Conditions of use—(1) Amount.* (i) For topical dermatological use: Clean affected areas and remove any encrusted discharge or exudate, and apply sparingly either ointment in a thin film.

(ii) For otic use: Clean ear canal of impacted cerumen, remove any foreign bodies such as grass awns and ticks, and instill three to five drops of petrolatum base ointment. Preliminary use of a local anesthetic may be advisable.

(iii) For infected anal glands and cystic areas: Drain gland or cyst and fill with petrolatum base ointment.

(2) *Indications for use.* (i) Topically: Use either ointment in dogs and cats for anti-inflammatory, antipruritic, antifungal, and antibacterial treatment of superficial bacterial infections, and for dermatologic disorders characterized by inflammation and dry or exudative dermatitis, particularly associated with bacterial or candidal (*Candida albicans*) infections.

(ii) Otitis, cysts, and anal gland infections: Use petrolatum base ointment in dogs and cats for the treatment of acute and chronic otitis and interdigital cysts, and in dogs for anal gland infections.

(3) *Limitations.* For mild inflammations, use once daily to once a week. For severe conditions, apply initially two to three times daily, decreasing frequency as improvement occurs. Not intended for treatment of deep abscesses or deep-seated infections. Not